

19



Europäisches Patentamt
European Patent Office
Office européen des brevets



11 Publication number:

0 463 551 B1

12

EUROPEAN PATENT SPECIFICATION

45 Date of publication of patent specification: **20.12.95** 51 Int. Cl.⁶: **A61B 17/58, A61B 17/16**

21 Application number: **91110021.2**

22 Date of filing: **19.06.91**

54 **Bone pinning system**

30 Priority: **28.06.90 US 545398**

43 Date of publication of application:
02.01.92 Bulletin 92/01

45 Publication of the grant of the patent:
20.12.95 Bulletin 95/51

64 Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

56 References cited:
EP-A- 0 059 044
EP-A- 0 338 779
DE-B- 1 029 528
DE-U- 8 800 197

73 Proprietor: **AMERICAN CYANAMID COMPANY**
One Cyanamid Plaza
Wayne, NJ 07470-8426 (US)

72 Inventor: **DiCarlo, Paul**
23 Sophie Lane
East Falmouth,
Massachusetts 02536 (US)

74 Representative: **Wächtershäuser, Günter, Prof.**
Dr.
Patentanwalt,
Tal 29
D-80331 München (DE)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

The invention relates generally to orthopedic surgery and provides a bone pinning device for treatment of bone fractures as defined in the preamble of Claim 1. Such a system is known from EP-A-0 059 044. In particular, the present invention relates to an improved apparatus and method for pinning and securing fractured bones together until they are healed.

BACKGROUND ART

Various methods and systems have been used to align, set and hold fractured bones together. Bone pins, screws, wires and guides of different types and styles are commonly used by surgeons to affix fractured bone pieces in place until they are healed. These bone fixation devices are typically removable or absorbable, although some are permanently installed in place. EP-A-0 338 779 discloses a bone nailer for inserting nails or screws into a bone.

In order to reduce trauma and recovery time, some devices and procedures have been developed which eliminate the need for making a major incision. The surgical pins or fasteners are installed into the bone with little or no prior incision. It is difficult to determine the precise depth of the pin or hole with some of these prior systems, and the end of the pin is often left exposed or protruding from the bone which can often cause discomfort or further complications.

DISCLOSURE OF INVENTION

The present invention relates to an improved surgical system and method for accurately installing and inserting bone pins to set and heal fractures. The applicator device and system allows accurate determination of the depth of the holes for the bone pins, as well as accurate placement of the pins. The pins preferably are absorbable and made of polyglycolic acid. They are selected or cut to a predetermined length prior to insertion and do not protrude from the bone or skin.

The applicator device has one or two guide tubes attached to a handle. A wire-type drill inserted through the guide tube is used to drill holes in the bone for the pins. One or more markings on the drill are matched or calibrated with a scale on a recess in the handle for accurate determination of the movement of the drill and thus the depth of each hole. Bone pins of appropriate diameters are selected and cut to the precise depth of the holes. The pins are placed in the applicator device which is used as an insertion guide. A plunger or push rod is used to forcibly push the bone pins into the

holes. The pins securely hold the fractured bone pieces in place until they become fused together.

Where a single tube application device is utilized, the procedure is repeated several times until the desired number of pins are installed in place. Where a two tube application device is utilized, a guide wire, drill or bone pin positioned in one hole can be used to keep the fractured bone pieces set and held together while a second hole is formed. This prevents any disturbance of the positioning of the bones due to withdrawal of the drill or guide wire. In a two or multiple tube application, it is possible to angle or skew the orientations of the tubes in order to allow the drills and pins to "wedge" the bone pieces together and thus aid in holding them in place.

In accordance with the present invention, it is a basic object to provide an improved bone pinning system to help hold fractured bones in place until they are healed. Another object of the invention is to provide a bone pinning system which accurately and precisely determines the depth of the drilled hole and thus allows accurate selection of the appropriate pin.

It is also an object of the invention to provide a relatively simple and easy to use bone pinning system which utilizes absorbable pins and prevents them from protruding outside the bone or skin. It is a still further object of the present invention to provide a bone pinning applicator which allows the fractured bone pieces to be held securely in position during the bone pinning drilling and installation procedure.

Other advantages and objects of the invention will become more apparent from the description of the drawings and preferred embodiments as set forth in the remainder of the specification.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 illustrates the present invention being used to drill a hole for a bone pin;

FIGURE 2 is a side view of the inventive applicator device and showing a bone pin for subsequent insertion into a bone;

FIGURE 3 illustrates the insertion of a bone pin into a drilled hole in a fractured bone;

FIGURE 4 illustrates a double tube applicator device in accordance with the present invention;

FIGURE 5 illustrates an embodiment of a double tube applicator device with angled or skewed guide tubes; and

FIGURE 6 is a side view of the applicator device as shown in Figure 5.

BEST MODE FOR CARRYING OUT THE INVENTION

Figures 1-3 illustrate a single tube applicator device and its use in accordance with the present invention. The applicator device is generally designated by the numeral 10. It has a handle 12 and a tube 14. The applicator device 10 is cannulated, that is, it has a channel or opening 16 extending throughout its length.

The handle 12 is preferably made of an auto-clavable metal (e.g. aluminum) or plastic, a disposable metal or plastic or any equivalent materials. The tube 14 is preferably made from a metal material (e.g. stainless steel) which has sufficient strength to meet the projected uses of the device 10 and also is auto-clavable.

The handle is generally circular in cross-section with a curved portion 18 at one end to aid the surgeon in manually holding and maneuvering it into position. A recess portion 20 is formed in the handle and has a scale or calibrated markings 22 on it. The markings 22 are preferably in millimeters, but they can be provided in thousandths of an inch or any convenient or appropriate scale for use by the surgeon.

The recess 20 is recessed to a depth where it intersects the opening 16 forming an open channel 24 in the handle.

The opening 16 has a cross-sectional size to allow a wire-type drill 30 (or guide wire) to be freely insertable and slidable within it. The drill 30 has a pointed tip 32 at one end. The opposite end 34 of the drill sufficiently protrudes beyond the end of the applicator device 10 and is adapted to be held in a mechanical or electrical drill (not shown).

The wire drill 30 has one or more marks 36 on it which are used to indicate its position relative to the scale 22. It is understood that any type of visible marking or fixed indication on the drill can be utilized to indicate its relative position relative to the handle. For example, the drill could have a colored ring around it at a certain point, or be provided in multiple colors and have a color separation line at a certain point. It is also understood in accordance with the present invention that the scale means could be provided on the drill and a marking of some type be positioned on the handle. It is also possible to use a guide wire in holding the bone pieces together temporarily after the hole is formed.

When the application device 10 is utilized, it is positioned against the skin or bone adjacent the fractured bone pieces 40 and 42. A wire drill 30 is then inserted in the central aperture 16 and used to drill a hole 44 in the two bone pieces. (A previously drilled hole 46 is also shown in Figure 1.) The depth D of the hole 44 is accurately determined by

the movement of the mark 36 on the drill relative to the markings on the scale 22. In this manner, the surgeon can drill each bone fixation pin hole to a precise and/or desired depth.

Once the hole is formed to the prescribed depth D, the bone pin 50 is selected and cut to a length L which matches the depth D. If a series of bone pins are provided or available of different lengths, it is possible to simply select one of an appropriate length. (If pins of a certain length are provided initially, then it may be possible depending on the circumstances for the surgeon to drill the holes to a depth to match the bone pins.) If desired, the length L can be any length less than the depth D of the hole so that the pin 50 will not protrude beyond the entrance of the hole 44, and/or will promote immediate bone growth at the entrance to the hole 44.

The actuator device 10 can be provided in a kit form with a plurality of bone pins of different lengths and cross-sectional sizes. A pin is selected which matches the diameter of the drill 30 which is used to drill the hole 44. The bone pin 50 is selected of the appropriate length L or cut to a desired length for use in the surgical procedure.

As mentioned earlier, the bone pins are preferably made of an absorbable material, such as polyglycolic acid (PGA). Absorbable surgical structural elements made of PGA are disclosed in United States Patent No. 3,739,773. It is, of course, possible with the present invention to also use bone pins made of metal or another suitable material.

The bone pins preferably are on the order of 1-4.5 mm in diameter, and the actuator device (handle and tube) is preferably about 6-12 inches in length.

Once the bone pin 50 is selected of the appropriate size and length, it is placed in the opening 16 in the handle 12 (as shown in Figure 2). Due to the recess 20, the pin can be inserted in the tubular opening 16 at the position shown in Figure 2. The pin 50 is then pushed through the handle 12 and hollow tube 14 into the hole 44 by means of an elongated plunger or push rod 52. This is shown in Figure 3. The forcing of the pin 50 into the drilled hole 44 compresses the bone pieces 40 and 42 together. The pin 50 holds the fractured pieces securely together until they are fused in place and healed. In Figure 3, a bone pin 54 is shown which has been previously installed in place in second hole 46.

After the bone pins 50, 54, etc. are installed in place, the push rod 52 and applicator device 10 are removed and the wound is closed or dressed as needed. The precise number of bone pins required to securely hold the bone pieces together and heal the fracture is determined by the type and severity

of the fracture and the desires of the surgeon. Typically two or more bone pins are utilized in most situations.

An alternate embodiment of the bone pin applicator device is shown in Figure 4. The device 60 has a handle portion 62 and a pair of parallel hollow tubes 64 and 66. With the exception of two tubes and their associated openings 16', 16" and channels 24' and 24", the device 60 is essentially the same as the device 10 described with reference to Figures 1-3. The device 60 is also used in substantially the same manner as device 10 to insert absorbable bone pins in place to hold fractured bone pieces 40' and 42' together.

A pair of wire-type drills 30 and 30' are used to drill the holes in the bone pieces for the bone pins. For this purpose the device 60 is used as a drill guide in the same manner as described above with reference to Figures 1-3. Markings 36 and 36' on the drills are used to determine the depths of the drilled holes relative to the calibrated scale 22 on the handle 62 of the device 60. The scale 22 is positioned in recess 20'.

The device 60 allows the surgeon to install two bone pins in the fractured bone pieces in a quick and simple manner. The device also allows the surgeon to retain one drill or guide wire in place in the bone through one of the tubes 64 or 66 while a bone pin is installed through the other tube. This causes the bone pieces 40' and 42' to be retained securely set and affixed in place by compression until the first bone pin is installed in place.

Figures 5 and 6 disclose another two-tube embodiment 68 of the invention. In this alternate embodiment, the two tubes 70 and 72 are positioned at an angle or in a skewed relationship relative to one another. The tubes 70 and 72 are connected to a handle 74 which, similar to handles 12 and 62, has a recessed portion 20' and one or more calibrated scales 22. As shown in Figure 5, it is preferable to provide two separate scales on this embodiment, one for each of the angled tubes.

The actuator device 68 is used in the same manner and for the same purpose as the devices 10 and 60 described above. The skewed insertion tubes 70 and 72 allow the wire-type drills, guide wires and subsequently installed bone pins to act to "wedge" the fractured bone pieces 40' and 42' together and help hold them securely in place until they are healed.

Although particular embodiments of the present invention have been illustrated in the accompanying drawings and described in the foregoing detailed description, it is to be understood that the present invention is not to be limited to just the embodiments disclosed, but that they are capable of numerous rearrangements, modifications and substitutions without departing from the scope of

the claims hereafter.

Claims

1. Device (10) for treating fractured bones by drilling a hole (44) and inserting a bone pin (50) said device comprising an elongated member (12,14) with a passageway (16) extending between an opening at the proximal end and an opening at the distal end of said elongated member facing the bone to be repaired, whereby said passageway is designed for slidably receiving an elongated drill (30) for drilling the hole

characterized in that

the elongated member is designed for being positioned against the skin or bone with its distal end and that for controlling and measuring the depth of the hole said elongated member has a view means (20), disposed proximate to said proximal end, for providing visual communication between the exterior of said elongated member and a portion of said first passageway and graduated markings (22), associated with said view means, for enabling alignment with the elongated drill to measure the depth of the hole formed in the bone and said elongated member defining an insertion port (24) distal to said proximal end, communicating with said first passageway, and at least as wide as the cross-sectional size of said first passageway, to enable lateral insertion of the bone pin into said first passageway through said insertion port for placement into the hole after the hole has been formed in the bone.

2. The device of Claim 1 in which said view means and said insertion port are mutually established by a recess formed in said elongated member distal to said proximal end.
3. The device of Claim 1 further including a handle attached to said elongated member for gripping by an operator of said elongated member.
4. The device of Claim 3 in which said handle is disposed near to said proximal end.
5. The device of Claim 1 in which said elongated member includes:
 - an elongated hollow handle member defining said proximal opening and having a second passageway along its length communicating with said proximal opening; and
 - an elongated hollow tubular member attached to the distal end of said handle mem-

ber, said tubular member defining said distal opening and having a third passageway along its length communicating with said distal opening and in axial alignment with said second passageway in said handle, said second and third passageways together establishing said first passageway.

6. The device in Claim 5 in which said handle member has a lateral recessed portion thereon intersecting said first passageway to establish said view means and said insertion port.
7. The device in Claim 6 in which said recessed portion is at least one-half as long as said handle member.
8. The device of Claim 6 in which said recessed portion has an elongated flat portion on which said graduated markings are positioned.
9. The device as claimed in Claim 1, characterized in that the drill includes calibration markings which may be aligned with said graduated markings of said elongated member.
10. The device of Claim 9, characterized by a plunger dimensioned to fit within said first passageway for driving the bone pin into the hole formed in the bone.

Patentansprüche

1. Vorrichtung (10) zur Behandlung von gebrochenen Knochen durch Bohren eines Lochs (44) und Einführen eines Knochennagels (50), wobei die Vorrichtung ein langgestrecktes Element (12, 14) umfaßt, mit einem Durchlaß (16), der sich zwischen einer Öffnung am proximalen Ende und einer dem wiederherzustellenden Knochen gegenüberliegenden Öffnung am distalen Ende des langgestreckten Elementes erstreckt, wobei der Durchlaß so gestaltet ist, daß er einen langgestreckten Bohrer (30) zum Bohren des Lochs verschiebbar aufnimmt, dadurch gekennzeichnet, daß das langgestreckte Element gestaltet ist, um es mit seinem distalen Ende gegen die Haut oder den Knochen anliegend zu positionieren, und daß das langgestreckte Element zur Steuerung und zum Messen der Tiefe des Lochs eine Sichteinrichtung (20) aufweist, die in der Nähe des proximalen Endes angeordnet ist, um für eine Sichtverbindung zwischen dem Äußeren des langgestreckten Elementes und einem Teil des ersten Durchlasses zu sorgen, sowie zur Sichteinrichtung gehörige Strichmarkierungen (22) zum Ermöglichen eines Ab-

gleichs mit dem langgestreckten Bohrer, um die Tiefe des im Knochen gebildeten Lochs zu messen, und daß das langgestreckte Element eine distal vom proximalen Ende gelegene Einführöffnung (24) begrenzt, die mit dem ersten Durchlaß in Verbindung steht und mindestens ebenso weit wie die Querschnittsabmessung des ersten Durchlasses ist, um ein laterales Einführen des Knochennagels durch die Einführöffnung in den ersten Durchlaß für ein Einbringen in das Loch zu ermöglichen, nachdem das Loch im Knochen gebildet worden ist.

2. Vorrichtung nach Anspruch 1, bei welcher die Sichteinrichtung und die Einführöffnung gemeinsam von einer Vertiefung gebildet werden, die distal vom proximalen Ende im langgestreckten Element ausgebildet ist.
3. Vorrichtung nach Anspruch 1, weiter enthaltend einen am langgestreckten Element angebrachten Griff zum Ergreifen durch eine Person, die das langgestreckte Element bedient.
4. Vorrichtung nach Anspruch 3, bei welcher der Griff nahe dem proximalen Ende angebracht ist.
5. Vorrichtung nach Anspruch 1, bei welcher das langgestreckte Element einschließt:
ein langgestrecktes hohles Griffelement, das die proximale Öffnung begrenzt und entlang seiner Länge einen zweiten Durchlaß aufweist, der mit der proximalen Öffnung in Verbindung steht; und
ein langgestrecktes hohles röhrenförmiges Element, das am distalen Ende des Griffelementes angebracht ist, wobei das röhrenförmige Element die distale Öffnung begrenzt und entlang seiner Länge einen dritten Durchlaß aufweist, der mit der distalen Öffnung in Verbindung steht und mit dem zweiten Durchlaß im Griff axial fluchtet, wobei der zweite und dritte Durchlaß zusammen den ersten Durchlaß bilden.
6. Vorrichtung nach Anspruch 5, bei welcher das Griffelement ein seitlich vertieftes Teilstück darauf aufweist, das den ersten Durchlaß kreuzt, um die Sichteinrichtung und die Einführöffnung zu bilden.
7. Vorrichtung nach Anspruch 6, bei welcher das vertiefte Teilstück mindestens halb so lang wie das Griffelement ist.
8. Vorrichtung nach Anspruch 6, bei welcher das vertiefte Teilstück einen langgestreckten fla-

chen Teilbereich aufweist, auf dem die Strichmarkierungen angebracht sind.

9. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Bohrer Kalibriermarkierungen enthält, die mit den Strichmarkierungen des langgestreckten Elementes abgeglichen werden können.

10. Vorrichtung nach Anspruch 9, gekennzeichnet durch einen Kolben, der so bemessen ist, daß er in den ersten Durchlaß paßt, um den Knochennagel in das im Knochen gebildete Loch zu treiben.

Revendications

1. Dispositif (10) pour traiter des os fracturés par perçage d'un trou (44) et insertion d'une broche (50) pour os, ledit dispositif comportant un élément allongé (12, 14) ayant un passage (16) s'étendant entre une ouverture située au niveau de l'extrémité proximale et une ouverture située au niveau de l'extrémité distale dudit élément allongé situé en vis-à-vis de l'os destiné à être réparé, de sorte que ledit passage est conçu pour recevoir de manière coulissante une mèche allongée (30) pour percer le trou,

caractérisé en ce que

l'élément allongé est conçu pour être positionné ayant son extrémité distale contre la peau ou l'os et en ce que pour commander et mesurer la profondeur du trou, ledit élément allongé a des moyens de visualisation (20), agencés à proximité de ladite extrémité proximale, pour donner une indication visuelle entre l'extérieur dudit élément allongé et une partie dudit premier passage et des marques graduées (22) associées auxdits moyens de visualisation, pour permettre un alignement avec la mèche allongée pour mesurer la profondeur du trou formé dans l'os et ledit élément allongé définissant un orifice d'insertion (24) distal par rapport à ladite extrémité proximale, communiquant avec ledit premier passage, et au moins aussi large que la dimension en coupe dudit premier passage, pour permettre l'insertion latérale de la broche pour os à l'intérieur dudit premier passage à travers ledit orifice d'insertion pour sa mise en place dans le trou après que le trou ait été formé dans l'os.

2. Dispositif selon la revendication 1, dans lequel lesdits moyens de visualisation et ledit orifice d'insertion sont établis mutuellement par une cavité formée dans ledit élément allongé, distale par rapport à ladite extrémité proximale.

3. Dispositif selon la revendication 1, comportant en outre une poignée fixée audit élément allongé pour être saisie par un opérateur dudit élément allongé.

4. Dispositif selon la revendication 3, dans lequel ladite poignée est disposée à proximité de ladite extrémité proximale.

5. Dispositif selon la revendication 1, dans lequel ledit élément allongé comporte :

un élément formant poignée creuse allongée définissant ladite ouverture proximale et ayant un deuxième passage suivant sa longueur, communiquant avec ladite ouverture proximale, et

un élément tubulaire creux allongé, fixé à l'extrémité distale dudit élément formant poignée, ledit élément tubulaire définissant ladite ouverture distale et ayant un troisième passage agencé suivant sa longueur, communiquant avec ladite ouverture distale et aligné axialement avec ledit deuxième passage situé dans ladite poignée, lesdits deuxième et troisième passages établissant ensemble ledit premier passage.

6. Dispositif selon la revendication 5 dans lequel ledit élément formant poignée a une partie latérale creusée agencée sur celui-ci, recouvrant ledit premier passage pour établir lesdits moyens de visualisation et ledit orifice d'insertion.

7. Dispositif selon la revendication 6, dans lequel ladite partie creusée a une longueur d'au moins la moitié dudit élément formant poignée.

8. Dispositif selon la revendication 6, dans lequel ladite partie creusée a une partie plate allongée sur laquelle sont positionnées lesdites marques graduées.

9. Dispositif selon la revendication 1, caractérisé en ce que la mèche comporte des marques de calibrage qui peuvent être alignées avec lesdites marques graduées dudit élément allongé.

10. Dispositif selon la revendication 9, caractérisé en ce qu'il comporte un piston plongeur dimensionné pour être agencé dans ledit premier passage pour entraîner la broche pour os à l'intérieur du trou formé dans l'os.

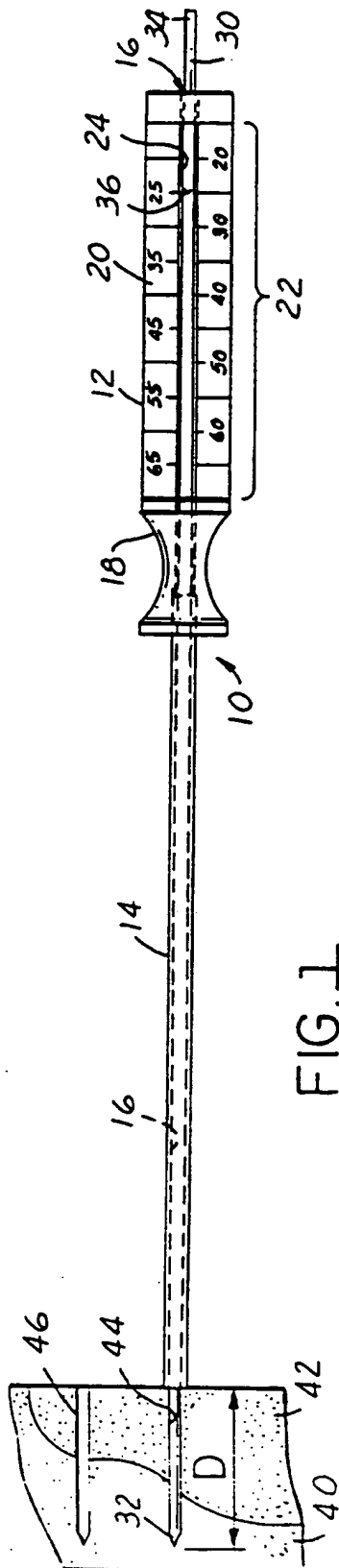


FIG. 1

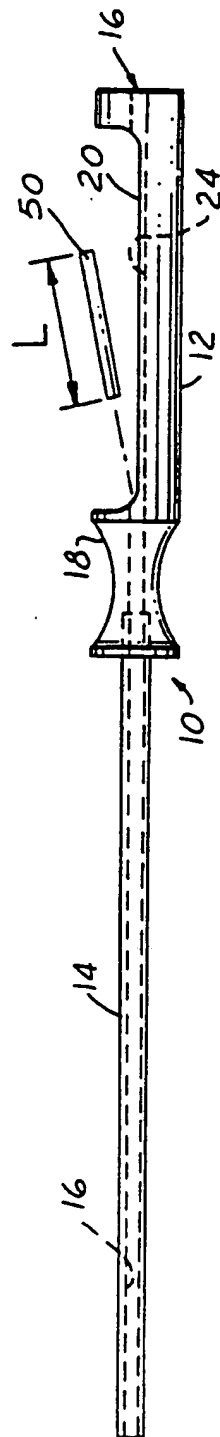


FIG. 2

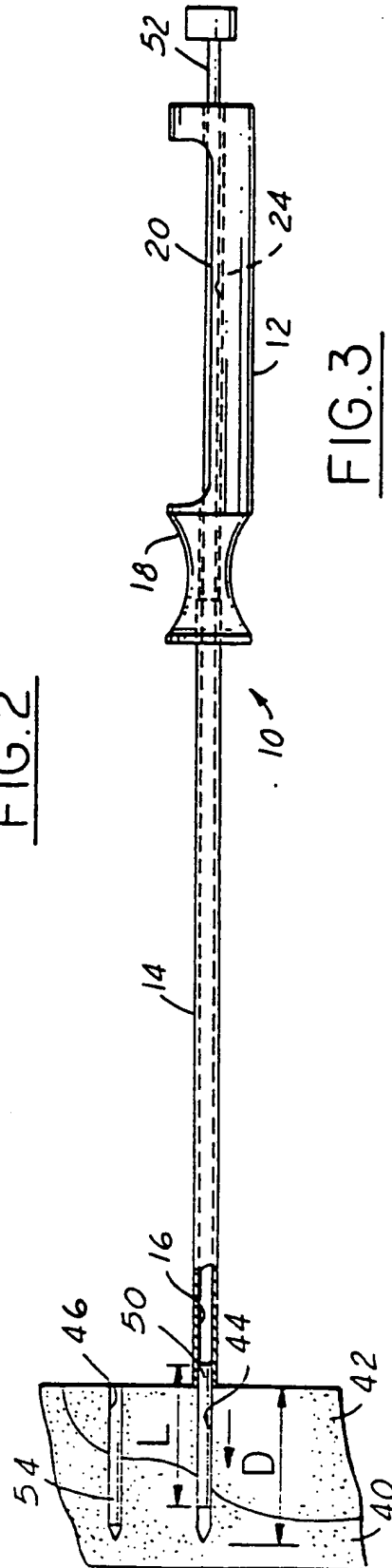


FIG. 3

